UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,095	02/09/2006	Kishore Udipi	PA1366 US	2491

28390 7590 06/07/2010

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER	
GULLEDGE, BRIAN M	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
06/07/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/595,095	UDIPI ET AL.	
	Examiner	Art Unit	
	Brian Gulledge	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Previous Rejections

Applicants' arguments, filed 15 February 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-13 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benz et al. (US Patent Application Publication 2003/0162905) in view of Shalaby et al. (US Patent Application Publication 2003/0199964) and Van Krevelen ("Properties of Polymers," 1990, Elsevier, 3rd Edition, Chapter 7, pages 189-225). Benz et al. discloses copolymers for coating medical devices (paragraph [2], lines 1-4). The copolymer is an A_nB block copolymer. The "A" block comprises vinyl pyrrolidone as at least one of the monomers in order to provide suitable lubricity to the device (paragraph [34], lines 1-8). The "A" block also can comprise other monomers in addition to the vinyl pyrrolidone, such as methacrylic esters (paragraph [35], lines 1-7). Benz et al. teaches that the "B" block is designed to be compatible with, and adhere to, the surface to be coated (paragraph [40], lines 1-8). Benz et al. further teaches mixing the above copolymer with secondary polymers to further modify the surface

coating (paragraph [31], lines 1-11). However, Benz et al. does not disclose the use of poly(vinyl acetate) for the "B" block, nor does Benz et al. disclose using a copolymer that comprises an alkyl methacrylate and vinyl acetate in the coating composition, as recited by instant claim 3.

Shalaby et al. discloses polymeric coated stents with a bioactive agent dispersed within the coating (abstract, lines 1-5). The stent disclosed addresses the problems that the drug-containing polymer may not adhere to the stent (paragraph [5], lines 8-11) and that the drug may elute too quickly (paragraph [5], lines 77-13). Shalaby et al. teaches that the coating comprises a copolyester made from vinyl acetate and butyl methacrylate (paragraph [9], lines 1-10), and that the individual blocks affect the properties of the whole polymer (paragraph [28], lines 1-17). Shalaby et al. further teaches that the vinyl acetate block (the "second segment") provides metal-adhering characteristic to the coating (paragraph [9], lines 1-6).

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made the A_nB block copolymer disclosed by Benz et al. with vinyl acetate as the "B" block. Shalaby et al. teaches that this block of a copolymer allows for adhesion of a polymeric coating to a stent, and Benz et al. teaches that this block in the disclosed polymer controls adhesion of the coating to the stent. And it would also have been *prima facie* obvious to have prepared a coating with both the terpolymer of Benz et al. and the copolymer taught by Shalaby et al., as they are both used for providing drug-eluting coatings for stents wherein the coating has improved adhesion to the stent. Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The

idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

The above references do not discuss the average solubility parameter values for the blend of the copolymers or the drug (if present), as recited by the instant claims. However, the solubility parameters for each of the individual polymeric blocks from which is the copolymers are prepared are all within the claimed range (see Van Krevelen table 7.5). As such, the copolymers would be expected to possess solubility parameters within the claimed range. Further, Van Krevelen discusses that two polymeric substances with similar solubility properties should be mutually soluble whereas when the differences between the solubility parameters increases there is a tendency away from dissolution (page 201, lines 1-15). Thus, while Benz et al. and Shalaby et al. are silent as to controlling and selecting the solubility profiles of the polymers (so that they are approximately equal), Van Krevelan et al. demonstrates that one of ordinary skill in the art would know that the difference between the solubility parameters could be used to predict solubility and miscibility of two or more substances, and that the solubility would be enhanced by having the solubility parameters for the different components of the blend relatively similar. Thus, the ordinary skill artisan would know how to optimize the relative proportions of monomers and polymers in order to achieve a combination that is miscible together, and form a blend for use in coating medical devices such as stents.

Claims 14 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benz et al. (US Patent Application Publication 2003/0162905), Shalaby et al. (US Patent Application Publication 2003/0199964), and Van Krevelen ("Properties of Polymers," 1990,

Elsevier, 3rd Edition, Chapter 7, pages 189-225), as applied to claim 13 above, and further in view of Sirhan et al. (US Patent Application Publication 2002/0082677). The coated stent taught by Benz et al. and Shalaby et al. teaches all of the limitations recited by the instant claims except for the stent having a parylene coating. Shalaby et al. also teaches all of the limitations of instant claims 22-24 except for the inclusion of rapamycin as the drug, though Shalaby et al. disclosed using anti-proliferatives as the active agent (paragraph [13]).

Sirhan et al. discloses vascular stents (paragraph [3], lines 1-6). Sirhan et al. discloses that the stents may comprise a barrier layer formed over the substrate structure to help control the release rate, such as a parylene barrier (paragraph [24], lines 1-12). Sirhan et al. further teaches the stents can be used to deliver immunosuppressant active agents, such as rapamycin (paragraph [22], lines 1-3).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the stent coating taught by Benz et al. and Shalaby et al. in order to provide a stent for delivering rapamycin, as the coating taught by Benz et al. and Shalaby et al. would allow the skilled artisan a method to control the rate of delivery of the active agent. Further, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used parylene to coat the substrate of the stent, as this would allow the skilled artisan to further control the rate of release of the bioactive agent.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612